ExPloring efficAcy, safeTy, and adHerence oF dIsease-modifyiNg antirheumatic Drugs through trajEctoRy model: the PATHFINDER study

First published: 11/04/2019

Last updated: 23/04/2024

Study Planned

Administrative details

PURI

https://redirect.ema.europa.eu/resource/37113

EU PAS number

EUPAS29263

Study ID

37113

DARWIN EU® study

No

Study countries

Italy

Study description

This project will evaluate the utilization, adherence, efficacy, and safety of disease modifying antirheumatic drugs employed for the management of rheumatoid arthritis in the Tuscan population by means of real world data. This research will identify patterns of utilization of rheumatoid arthritis treatments and their predictors, and it will explore the relationship of these trajectories with endpoints of effectiveness and safety.

Study status

Planned

Research institutions and networks

Institutions

University Hospital of Pisa

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

Marco Tuccori

Study contact

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Primary lead investigator

Marco Tuccori

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 29/03/2019

Actual: 29/03/2019

Study start date
Planned: 13/05/2019

Date of final study report
Planned: 31/12/2021

Sources of funding

- Other

More details on funding

Pisa University Hospital

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Other study registration identification numbers and links

Protocol n.18724 of Tuscan Regional Ethics Committee for Clinical Trials

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Main study objective:

This research will identify patterns of utilization of rheumatoid arthritis treatments and their predictors, and it will explore the relationship of these

trajectories with endpoints of effectiveness and safety.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(L04AA24) abatacept

abatacept

(L04AA29) tofacitinib

tofacitinib

(L04AA37) baricitinib

baricitinib

(L04AB) Tumor necrosis factor alpha (TNF-alpha) inhibitors

Tumor necrosis factor alpha (TNF-alpha) inhibitors

(L04AC07) tocilizumab

tocilizumab

(L04AC14) sarilumab

sarilumab

Medical condition to be studied

Rheumatoid arthritis

Population studied

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Estimated number of subjects

3000

Study design details

Outcomes

We will identify trajectories of utilization of bDMARD and tsDMARD over the time of follow-up (3 years). Trajectories will be identified by using trajectory model approach, patients will be classified according to their most likely pattern of adherence (i.e. the trajectory that the patient has the highest probability of belonging to). We will test several variables as predictors. a) Validate the selected RA patientsb) Investigate effectiveness over the "off treatment" and "on treatment" periodsc) Evaluate the occurrence of ED admission/hospitalization over the "off treatment" and "on treatment" periods d) Assess the occurrence of ED admission/hospitalization related to trajectories

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Data analysis plan

Validation analysis: sensitivity, specificity, positive and negative predictive value.Drug-utilization analyses: trajectory model approach.Effectiveness: descriptive analysis.Safety analyses: proportion and time free from events.

Data management

ENCePP Seal

This study has been awarded the ENCePP seal

Conflicts of interest of investigators

CV MT.pdf(682.55 KB)

DOI.pdf(2.13 MB)

Composition of steering group and observers

study group_DoIForms and CV (RG_CB_EL_IC).pdf(2.34 MB)

Signed code of conduct

Declaration of compliance.pdf(468.25 KB)

Signed code of conduct checklist

Checklist Code of conduct.pdf(4.96 MB)

Signed checklist for study protocols

Checklist study protocol.pdf(3.37 MB)

Data sources

Data source(s)

ARS Toscana

Data source(s), other

ARS

Data sources (types)

Administrative healthcare records (e.g., claims)

Drug dispensing/prescription data

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No